

REMARKS

The Examiner has raised the following objections and rejections, summarized below in the order in which they are addressed:

- I.** Claims 35 and 47 are objected to for informalities;
- II.** Claims 35, 47, 62-63, 65-68, 71, 73, and 78-84 stand rejected under 35 U.S.C. §112, second paragraph as allegedly failing to particularly point out an distinctly claim the subject matter which the Applicants regard as their invention;
- III.** Claims 35, 47, 62, 63, 66, 71, and 72 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No, 4,994,368 to Goodman (hereinafter "Goodman");
- IV.** Claim 65 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Goodman in view of U.S. Patent No. 5,270,184 to Walker (hereinafter "Walker");
- V.** Claim 73 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Goodman in view of U.S. Patent No. 4,683,195 to Mullis (hereinafter "Mullis");
- VI.** Claims 35, 47, 62, 63, 65-68, 71-73, and 78-84 stand rejected on the grounds of nonstatutory obviousness-type double patenting over U.S. Patent No. 6, 458,535;
- VII.** Claims 35, 47, 62, 63, 65-68, 71-73, and 78-84 stand rejected on the grounds of nonstatutory obviousness-type double patenting over U.S. Patent No. 5,994,069;
- VIII.** Claims 35, 47, 62, 63, 65-68, 71-73, and 78-84 stand rejected on the grounds of nonstatutory obviousness-type double patenting over U.S. Patent No. 6, 913,881.

I. Informalities

Claims 35 and 47 are objected to for informalities. The Examiner asserts that "cleaved second probe" in steps b) and c) of Claim 35, and in Claim 47 should be "the cleaved second probe."

For business reasons and without acquiescing to the Examiner's arguments, and reserving the right to prosecute the original or similar claims in one or more future applications, Claims 35

and 47 are each amended to recite "the cleaved second probe." The amendments to the claims made herein do not narrow the scope of the claims within the meaning of *Festo*¹ or related cases.

II. 35 U.S.C. §112, second paragraph

Claims 35, 47, 62-63, 65-68, 71, 73, and 78-84 stand rejected under 35 U.S.C. §112, second paragraph as allegedly failing to particularly point out and distinctly claim the subject matter which the Applicants regard as their invention. Specifically, the Examiner asserts that Claims 35 and 62 and dependent claims are vague and indefinite in that it is unclear how a second cleavage structure comprising a second probe can be formed without a step that hybridizes the second probe oligonucleotide to said cleaved unpaired regions. Office Action page 3-4.

For the reasons recited in the Amendment and Response filed on March 23, 2006, and incorporated herein by reference, Applicants respectfully submit that the specification provides ample instruction on the formation of cleavage structures, and that the second cleavage structure of the present invention is not limited by any particular relationship between the cleaved unpaired region and the second probe, so long as the second cleavage structure comprises them both.

Nonetheless, for business reasons and without acquiescing to the Examiner's arguments, and reserving the right to prosecute the original or similar claims in one or more future applications, Claim 35 is currently amended to recite "wherein said second cleavage structure is formed when said cleaved unpaired region is hybridized to said second probe, or when said cleaved unpaired region and said second probe oligonucleotide are both hybridized to a second target polynucleotide" and Claim 62 is currently amended to recite "wherein said second cleavage structure is formed when said non-target cleavage product is hybridized to said probe oligonucleotide, or when said non-target cleavage product and said probe oligonucleotide are both hybridized to a second target nucleic acid." Support for the present amendment is found, *e.g.*, in Figs. 96 and 97. In the embodiment shown in Figure 96, the second cleavage structure comprises a cleaved unpaired region (shown as "Cut Probe 1") from cleavage of the first cleavage structure, and a second probe (shown as "Probe 2"), each hybridized to a second target polynucleotide. The embodiment shown in Figure 97 provides an embodiment in which the

¹ *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831 (2002)

cleaved unpaired region and the second probe hybridize to each other in the second cleavage structure.

Applicants submit that the claims as amended satisfy the requirements of 35 U.S.C. §112, second paragraph and therefore respectfully request that these rejections be removed.

35 U.S.C. §102(b)

III. Claims 35, 47, 62, 63, 66, 71, and 72 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Goodman, which discloses the use of restriction enzymes to cleave probes for the detection of target nucleic acids. See, *e.g.*, Table II in columns 10-12 for discussion of site-specific restriction enzymes.

Applicants respectfully disagree that Goodman anticipates the pending claims. Nonetheless, for business reasons and without acquiescing to the Examiner's arguments, and reserving the right to prosecute the original or similar claims in one or more future applications, Applicants herein amend Claims 35 and 62 to recite that the cleavage agent comprises a 5' nuclease. Claims 47 depends from Claim 35 and Claims 63, 66, 71 and 72 each depend from Claim 62. As such, these dependent claims incorporate all of the elements of the amended independent claims. This limitation was previously recited in Claim 67, which is canceled herein, and is not new matter.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP 2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d. 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Goodman does not recite use of a cleavage agent comprising a 5' nuclease. As such Goodman fails to recite every element of the instant claims and thus cannot anticipate these claims under 35 U.S.C. §102. Applicants therefore respectfully request that these rejections be removed.

35 U.S.C. §103(a)

Prima facie obviousness requires that the combination of reference contain a teaching or suggestion of all the limitations of the claims. A showing of obviousness will fail if this element is not met. MPEP §2143. Applicants submit that the combinations of the Goodman with Walker and with Mullis fail to teach or suggest all the elements of the instant claims.

IV. Claim 65 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Goodman in view Walker. As discussed above, Goodman does not recite the use of a cleavage agent comprising a 5' nuclease, as recited in the instant claims. Walker does not cure this deficiency. As this recited combination of references fails to teach or suggest each element of the instant claims, Applicants submit that these references cannot be combined to create a case for prima facie obviousness of Claim 65 and respectfully request that this rejection be removed.

V. Claim 73 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Goodman in view of Mullis. As discussed above, Goodman does not recite the use of a cleavage agent comprising a 5' nuclease, as recited in the instant claims. Mullis does not cure this deficiency. As this recited combination of references fails to teach or suggest each element of the instant claims, Applicants submit that these references cannot be combined to create a case for prima facie obviousness of Claim 73 and respectfully request that this rejection be removed.

Obviousness-Type Double Patenting

VI. Claims 35, 47, 62, 63, 65-68, 71-73, and 78-84 stand rejected on the grounds of nonstatutory obviousness-type double patenting over U.S. Patent No. 6, 458,535;

VII. Claims 35, 47, 62, 63, 65-68, 71-73, and 78-84 stand rejected on the grounds of nonstatutory obviousness-type double patenting over U.S. Patent No. 5,994,069;


VIII. Claims 35, 47, 62, 63, 65-68, 71-73, and 78-84 stand rejected on the grounds of nonstatutory obviousness-type double patenting over U.S. Patent No. 6, 913,881.

As each of these patents and the instant application are co-owned by the present Assignee, Applicants herein file a terminal disclaimer to obviate these rejections, and respectfully request that these rejections be removed.

CONCLUSION

For the reasons set forth above, it is respectfully submitted that all objections and rejections should be removed and Applicant's claims should be passed to allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourages the Examiner to call the undersigned collect at (608) 218-6900.

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